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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,173	01/28/2004	John E. Ahern	B0410/7283D1	4427

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EXAMINER	
GHERBI, SUZETTE JAIME J	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,173	AHERN, JOHN E.	
	Examiner	Art Unit	
	Suzette J. Gherbi	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/28/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment dated 2/16/05 has been received in application serial number 10/766,173. Claims 2 and 24-33 have been canceled.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3-6, 13, 17-20, 22-27 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al. 6,432,126. Gambale et al. discloses the invention as claimed noting figures 1-9 comprising: An implant for treating biological tissue with a therapeutic material associated with a scaffold structure that is implantable within tissue; wherein the scaffold has an interior chamber (14) with at least one opening (20) wherein the therapeutic material is associated with the interior of the scaffold; an exterior surface wherein the therapeutic material is associated with the exterior surface; wherein the therapeutic material defines a plurality of cells or tissue; (see col. 2, lines 44-45 and lines 66-67; col. 3, lines 36-58; col. 4, lines 12-19, lines 38-39); wherein the

scaffold comprises a coil body (see figure.6b); a mesh tube, porous pellet (see figures 8a-9b); wherein the scaffold can be made of many materials including stainless steel, or biodegradable polymer (see col. 7, lines 37-40). However, Gamble does not specify that the scaffold is "rigid". It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device to be rigid because Gamble discloses in col. 7,lines 35-38 that the implant may be "*formed from any material having the requisite strength, when configured in the chosen shape to* ***resist*** *substantial compression by contracting tissue that will surround the implant*" and the device can be made of stainless steel (col. 7,line 39) and this is the same material as described by applicant as being a "rigid material".

4. Claims 7-11, 16, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al. in view of Cafferate 6,689,121. Gambale et al. has been disclosed above however Gambale et al. does not specify the phrase *therapeutic material suspended in a liquid* and while Gambale et al. does disclose that therapeutic agents can range from cells, to blood to drugs, they are not specify the therapies. Cafferate teaches a device for treating ischemia, which utilizes therapies such as precursor cells, stem cells, cardiomyocytes, DNA and skeletal myoblast (see col. 3, lines51-55; col. 4 lines 1-5; claim 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the therapies as taught by Cafferata in the device of Gambale et al. because they all aid in the promotion of angiogenesis and this listing of drugs

are just a narrow range of drugs well known for there therapeutic properties. It is also obvious that nitinol is a shape memory material and Gambale et al. states that shape memory materials can be utilized to form the scaffold device. It is also obvious to one having ordinary skill in the art that the therapies of Gambale et al. are in a liquid suspension because Gambale states in col. 6 to 7, lines 61-67; 1-3 that the angiogenic substance may be delivered into the capsule with a hypodermic need and syringe...rendering it obvious that the substance is in some type of liquid suspension and delivered after implantation.

5. Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al. in view of Slepian 5,575,815. Gambale et al. has been disclosed above however Gambale et al. does not specify joining the therapeutic material to the scaffold by an adhesive or that the materials is maintained in a gel form. Slepian et al. teaches local polymeric gel therapy and drug adhesives. It would have been obvious to one having ordinary skill in the art at the time the invention was made to associate the therapeutic material via adhesive or maintain the material in a gel form, because the tacky characteristics would provide good adhesion to the device without adding additional structural bulk to the implant.

Response to Arguments

6. The Double Patenting rejection of claims 1-27 and 32 is withdrawn.

7. Applicant's arguments filed 2/16/05 have been fully considered but they are not persuasive. Applicant has amended the claims and contends that Gambale et al. device does not have the limitation of being "rigid". The examiner would like to point to specific passages in applicant's specification.

Section [0012] states:

The angiogenic implant comprises a device that is implanted into tissue and is configured to promote angiogenesis in the subject tissue. The angiogenic implant device may be formed in a variety of configurations, but should comprise a structure, **scaffold or frame, flexible or rigid**, having a region where the therapeutic material may be fostered and retained in association with the implant device, in, on, or around its structure. The retention region may be on the interior or exterior of the device. However, the device should be configured to permit communication between the associated therapeutic material and the surrounding tissue into which the device has been implanted. Blood, carrying nutrients must be permitted to flow to and from the therapeutic materials, if they are biological in nature, such as tissue, cells or cell material, so that the metabolic activity of the biological structures is sustained for a therapeutically effective time. After implantation of the angiogenic implant, new and recruited blood vessels will grow to the area of the implant site to supply the therapeutic materials with nutrients.

Further section [0066] states:

Device flexibility affects the tissue's function after placement of a plurality of devices. More flexible devices move more freely with surrounding tissue and, therefore, affect its function less prominently. However, it is recognized that that some resistance to tissue movement by the device is desirable to help irritate the tissue and cause an injury response. **The devices herein described are configured to be flexible, so as not to impede muscle function, yet provide sufficient fortitude to sustain a fibrin retention region and to irritate the tissue. For example, the tubular devices described herein may be constructed from 316 stainless steel filament** on the order of approximately 0.001"-0.002" in diameter.

And sections [0070 and] further reiterates:

"The **flexible** coils can be temporarily elastically deformed to permit loading of the material into the interior chamber of the device."

8. It is the examiners observation that the term "rigid" is only mentioned twice in applicants' disclosure without any type of criticality mentioned and in fact the invention primarily focuses on a device that is flexible. It is also the examiners opinion that Gambale's alleged flexible device is what applicants' invention appears to want to attain. It is further noted that the materials of Gambale invention are parallel to the materials in applicants' invention and can therefore achieve a "rigid" device. As pointed out above Gambale et al. material must be able *to **resist** substantial compression* and therefore obviously rigid. The structures as currently claimed are met by the office action described above.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

12. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Suzette J-J Gherbi
04 August 2005

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700